DETAILED ACTION

Applicants' arguments, filed March 25, 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

Claims 7-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer (US Patent 5,624,906). The rejection is maintained.

Applicant's Arguments

Applicant argues the particular combination of glycols recited in Claim 7 is a critical feature that results in unexpected results that one having ordinary skill in the art could in no way predict. The treatment composition comprising the claimed components possesses improved operability and penetrability of the treatment composition and

improved soaking properties for its administering to teeth so that bacterial intraoral diseases can be treated without depending on removal of living tissues. Nothing in the prior art would lead one having ordinary skill in the art to expect this result. Therefore, even if *prima facie* case of obviousness were established, the unexpected result would rebut any such case.

In regard to Claim 8, Applicant argues that Claim 8 depends from Claim 7, and further defines additional technical features of the present invention. In particular, Claim 8 recites ratios of each component, which cited reference is silent about.

In the Declaration discussed below, it is seen that the compositions encompassed by the instant claims comprising polyethylene glycol (PEG) 400, PEG600, PEG4000 and propylene glycol (PG) penetrates not only for a long distance, but also spans a wide area. Thus, it appears from both the earlier declaration and the newly submitted declaration that the base including the particular combination of PEG 400, PEG 600, PEG 4000, and PG of the claimed composition possesses superior penetrability, which eliminates removal of living tissues to treat bacterial intraoral diseases. Applicant respectfully submits Claim 7 is allowable over the cited references.

Examiner's Response

It is submitted that the results presented by Applicant have specific amounts of each component. Applicant has not provide sufficient evidence to support that the

assertion of unexpected results would occur when each of the components are used in different amounts as encompassed by instant claim 7. For instance it cannot be concluded from the results submitted that a composition comprising 1% polyethylene glycol 600 would yield similar effects as that used in the Experiments by Applicant. Therefore the claim is not commensurate in scope with Applicant's alleged unexpected results.

In regard to claim 8, the claim does not disclose the amount of polyethylene glycol 4000. The instant claim encompasses compositions comprising polyethylene glycol 4000 in varying amounts including an amount of 0.05% and there appears to be no evidence to support that Applicant's alleged unexpected results would occur when PEG 4000 is in this amount. Applicant has failed to show that these alleged unexpected results will occur in mixtures of all different amounts of each component that Applicant asserts is essential.

In regard to the results in the Declaration, there is no comparison of the effect of a composition comprising only PEG 600 has on penetration lengthwise and widthwise. Although it appears that PEG 600 (Sample 5) has the same effect as water (Sample 1) as seen in the Declaration comprising Experiment 1 filed November 9, 2009, Declarant makes no correlation between the results of Sample 5, Sample 7 and Sample 8, and the depth direction of Sample 8 does not appear to be given quantitatively as in the cases of Samples 5 and 7 (7 being the same as Sample 3 as asserted by Applicant).

Discussion of Examiner's Response to Declaration

Applicant's Arguments Regarding Efficacy of PEG 400 and PEG 4000 alone

The Examiner indicated that data should be submitted for a composition comprising PEG or PEG 4000 alone. However, as described in Applicant's specification from page 10, lines 15 to page 11, line 6 and the Declaration, the composition comprising PEG 400 or PEG 4000 alone, unlike the claimed composition, does not provide ease of loading onto administering tools and administering to teeth, or sterilizing effect against fungi. Accordingly, the composition comprising PEG 400 or PEG 4000 alone would be inoperable and have no efficacy for the intended purpose. Sample 1 which consists of water is merely a control to evaluate the penetrability of Sample 2 to 6, and is not a sample for evaluation as a treatment composition.

Examiner's Response Regarding Efficacy of PEG 400 and PEG 4000 alone

In regard to PEG 400 and PEG 4000 not providing ease of loading, this assertion does not appear to be in the specification on pages 10 to 11 as asserted above by Applicant. In regard to a solution with only 400 as discussed in the Declaration, water was used as a control. Although this is only a control, Applicant used water in the experiments and therefore it would appear that PEG 400 could also be used in the same manner. In regard to PEG 4000 Applicant's arguments appear to be persuasive.

Applicant's Arguments Regarding Experiment 2

It is asserted that, as explained by the inventor in a Declaration filed herewith, the conditions for Experiments 1 and 2 are the same, and the migration distance of Sample 7 is the same as the migration distance of Sample 3.

Examiner's Response Regarding Experiment 2

The Examiner submits that although Samples 3 and 7 are the same, it is not disclosed what the distance for Sample 8 (which is the instant invention). Therefore it is difficult to determine if the differences are unexpected or additive.

Declaration under 37 CFR 1.132 by Toyohiko Takushige

It is submitted that the Declaration discloses that Sample 8 actually has a longer migration distance than Sample 7, but because of the limitation of the length of the tooth root, the difference in migration distance is actually not that large. Further, as stated in the Declaration, the inventor carried out new experiments to evaluate the movement range (in particular, in the direction of the width of the tooth root).

In regard to the New Experiment, Sample 9 (PEG400:PEG4000:PG = 25:25:50) moved to the vicinity of the tip in the direction of the length of the tooth root and the portion over which it spread in the width direction was only a narrow area in the vicinity of the base portion of the tooth root and the tip. In contrast, Sample 10 (PEG400:PEG60:PEG4000:PG = 19:13:24:44) moved to the vicinity of the tip in the

length direction of the tooth root, and further, the portion over which it spread in the width direction spans a wide area from the base portion of the tooth root to the tip.

From this, it can be understood that the claimed treatment composition comprising PEG400, PEG600, PEG4000 and PG is capable to obtain the effect that the composition penetrates not only for a long distance, but also spans a wide area. Thus, it appears from both the earlier declarations and the newly submitted declaration that the base including the particular combination of PEG 400, PEG 600, PEG 4000, and PG of the claimed composition possesses superior penetrability, which eliminates removal of living tissues to treat bacterial intraoral diseases.

Examiner's Response to the Declaration under 37 CFR 1.132 by Toyohiko Takushige

In regard to Examples 7 and 8, it is not clear if this better result is additive or unexpected, based on the addition of PEG 600. The disclosure of sample 5 in the previous Declaration does not provide an adequate comparison because a quantitative result does not appear to be disclosed for Example 8. Further, although it appears that PEG 600 has the same effect as water as seen in the Declaration comprising Experiment 1 filed November 9, 2009, Declarant makes no correlation between the results of Sample 1 (the control), Sample 5, Sample 7 and Sample 8, and as stated above, the depth direction of Sample 8 does not appear to be given quantitatively as in the cases of Samples 5 and 7 (7 being the same as Sample 3 as asserted by Applicant).

In regard to the results for 9 and 10, it does appear that the combination of PEG400, PEG600, PEG4000 and PG having a ratio of 19:13:24:44, PEG400:PEG600:PEG4000:PG, does yield better results than that of PEG400:PEG4000:PG having a ratio of 25:25:50, yet Declarant has not shown the effect of PEG 600 on the width of the tooth. Therefore it cannot be independently concluded that the results are not additive.

Even if, for *arguendo*, the results disclosed by the declaration were concluded to be unexpected, the results are not commensurate in scope with the instant claims. Although Declarant asserts that the amount PEG 4000 is not important, it has not been shown that the alleged unexpected results are obtained from any amount of PEG 4000. Further it appears that the Declarant asserts that PEG 4000 is an essential component and therefore it would appear that the amount would actually be critical to the results. Further, claim 7 does not recite amounts for any of the components or ratios, whereas the Declaration discloses each component in specific ratios. Therefore the Declaration is insufficient to overcome the rejection.

Claims 7 and 8 are rejected.

Claim 1-6 and 13-16 are withdrawn.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612